



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Eugen Koren and Mirna Koscec

Serial No.: 08/970,045 Group Art Unit: 1645

Filed: November 13, 1997 Examiner: P. Duffy

For: ANTIBODIES TO LIPOPROTEINS AND APOLIPOPROTEINS  
AND METHODS OF USE THEREOF

Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

**DECLARATION OF AVAILABILITY OF DEPOSIT**

Sir:

I, Patrea L. Pabst, representing the assignee of the above-identified application, the Oklahoma Medical Research Foundation, by virtue of an assignment from the inventors recorded in the parent application U.S. Serial No. 08/268,809 filed June 30, 1994, at Reel 7202, frame 865, hereby declare that:

1. The hybridomas described at pages 51-52 and claim 4 of the application, HB<sub>3</sub>C<sub>B</sub><sub>3</sub>, and at page 74 and claim 5 of the application, RCB<sub>3</sub>M<sub>1</sub>D<sub>4</sub>, were deposited by the Oklahoma Medical

795363

OMRF143con 20487/214

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FILING DATE: November 13, 1997  
DECLARATION OF AVAILABILITY OF DEPOSIT

Research Foundation, the assignee of the above-identified application, with the American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD, prior to filing of the priority application, U.S. Serial NO. 08/268,809, on April 8, 1994. The deposits were assigned ATCC numbers HB11612 and 69602, respectively.

2. The Oklahoma Medical Research Foundation and the inventors have contracted with the American Type Culture Collection, and agreed pursuant to 35 U.S.C. §112 and MPEP §608.01(p) (C), that:

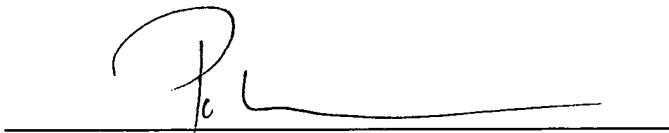
- (a) during the pendency of the application in the U.S. Patent and Trademark Office, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request of the deposit or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever

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become not viable.

3. The contract with the ATCC and deposit forms are attached.

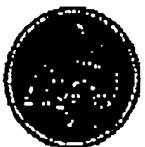
4. I declare that all statements made herein of my own knowledge are true. These statements are made with the knowledge that willful false statements are punishable by fine or imprisonment under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



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Patrea L. Pabst  
Registration No. 31,284

Date: January 28, 1999



# American Type Culture Collection

11301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301) 270-4200 Telex: 894-400 ATCCNORTH • FAX: 301-770-3327

## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

#### RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Dr. Eugen Koren  
Oklahoma Medical Research Foundation  
825 NE 13th Street  
Oklahoma City, OK 73104

Deposited on Behalf of: Dr. Eugen Koren, Oklahoma Medical Research Foundation

Identification Reference by Depositor:

ATCC Designation

Escherichia coli (TG 1), R<sub>c</sub>B<sub>s</sub>M<sub>D</sub><sub>s</sub>  
Murine hybridoma cell line, HB<sub>s</sub>cB<sub>s</sub>

69602  
HB 11612

The deposit was accompanied by:  a scientific description  a proposed taxonomic description indicated above.

The deposit was received April 8, 1994 by this International Depository Authority and has been accepted.

#### AT YOUR REQUEST:

We will not inform you of requests for the strain.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested April 12, 1994. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Bobbie A. Brandon

Date: April 12, 1994

Bobbie A. Brandon, Head, ATCC Patent Depository

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Form BP4/9

AUG 25 '99 01:12 PM Budapest Treaty Deposits

American Type Culture Collection

12301 Parkview Drive • Rockville, MD 20852 USA • Telephone: (301) 435-1200 • Telex 908-314-ATCC • FAX: (301) 770-2517

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF  
BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE  
DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

E. coli (TG 1)

\*1. Name of deposit (microorganism, cell, seed, plasmid, etc.)

2. Strain designation given by the depositor (number, symbols, etc.) RCB 3M1D4

3. Is this an original deposit under the Budapest Treaty? Yes

4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty? (If so, indicate ATCC designation.) No

5. Is this deposit a mixture of microorganisms or cells? No

6. Details and conditions necessary for the cultivation of the strain, for its storage and for testing for viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence. Reculture overnight at 30°C in SOB medium containing 0.1 mg/ml ampicillin and 0.1 M glucose (SOBAG). Alternatively, reculture on 1.5% Bacto Agar-SOBAG plates at 30°C overnight.

7. An indication of the properties of the strain which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties. The depositor is not aware of any health or environment risk out of ordinary risks inherent to E.coli.

\*8. It is recommended that sufficient description be provided to allow the ATCC to confirm that the strain deposited generally conforms to that which the depositor states is being deposited (i.e., Gram negative rod).

Gram negative rod

a. For cell culture deposits please complete. Is the cell being cultured in the presence of antibiotics? (If so list the antibiotics)

b. For hybridoma deposits please complete. What is the isotype of antibody produced?

\*9. Is this strain zoopathogenic? phytopathogenic?

\*10. Does this strain contain plasmids relevant to the patent process? Yes  
If so, what physical containment level is required [National Institutes of Health Guidelines involving Recombinant DNA Molecules (i.e., P1, P2, P3 and P4 facility)]? P1

\*11. Isolated from?

\*The answers to these questions are recommended but not required.

FOR ATCC USE ONLY	
ATCC DESIGNATION _____	
DATE CULTURE RECEIVED _____	
DATE VIABILITY TEST COMPLETED _____	

NOTE: 10 years' storage: \$600 = 10 years' additional \$130 = Viability testing \$100 to \$150 depends upon material. • Deposit ATCC number \$13 • Return sample for approval if not submitted freeze-dried \$20 • Prepare additional samples of cells/hybridomas \$500

STORAGE: cultures are stored for 30 years from date of deposit and for five years after the last request for a sample, as required under the rules of patent offices in most countries.

# American Type Culture Collection

100 Parklawn Drive • Rockville, MD 20853 USA • Tel: 301-533-5400; Fax: 301-774-2557

**TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF  
BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE  
DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE**

\*1. Name of deposit (microorganism, cell, seed, plasmid, etc.) Marine Hybridoma cell line

2. Strain designation given by the depositor (number, symbol, etc.) HB2cB3

3. Is this an original deposit under the Budapest Treaty? Yes

4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty? (If so, indicate ATCC designation.) No

5. Is this deposit a mixture of microorganisms or cells? No

6. Details and conditions necessary for the cultivation of the strain, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence.

Cultivation in RPMI 1640 + 10% fetal bovine serum + L-glutamine (5mM) + Penicillin (100units/ml)  
+ streptomycin (100 mcg/ml)

7. An indication of the properties of the strain which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties. The depositor is not aware of any health or environment risks

8. It is recommended that sufficient descriptive be provided to allow the ATCC to confirm that the strain deposited generally conforms to that which the depositor states is being deposited (i.e., Gram negative rod).

Round shaped hybridoma cells slightly adherent

a. For cell culture deposits please complete. Is the cell being cultured in the presence of antibiotics (if so list the antibiotics) Penicillin 100 units/ml, Streptomycin 100 mcg/ml

b. For hybridoma deposits please complete. What is the isotype of antibody produced? IgG1 (kappa)

9. Is this strain zoopathogenic? ..... phytopathogenic? .....

10. Does this strain contain plasmids relevant to the patent process? .....  
 If so, what physical containment level is required (National Institutes of Health Guidelines involving Recombinant DNA Molecules (i.e., P1, P2, P3 and P4 facility))?

11. Isolated from? .....

\*The answers to these questions are recommended but not required.

FOR ATCC USE ONLY	
ATCC DESIGNATION _____	
DATE CULTURE RECEIVED _____	
DATE VIABILITY TEST COMPLETED _____	

FEE: 10 years' storage \$600 + 10 years' certification \$100 + \$100 deposit/renewal fee + Expedited ATCC number \$10 = Renewal sample for approval if not submitted frozen or freeze-dried \$70 + Preprint additional samples of each hybridoma \$200  
 STORAGE: Cells are stored for 10 years from date of deposit and for five years after the last request for a sample, as required under the rules of patent offices in all countries.  
 Form BP1 (Page 1 of 2)

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FEB-02-00 18:11 FROM:

ID:

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4. In addition to those strains to sample under the Budapest Treaty and the European Patent Convention, do you wish the strain made available to:

a. Anyone who requests a culture (no restrictions on distribution from date of deposit or conversion to Budapest)?  
No

b. Requests to satisfy Patent Offices in countries not signatory to the Budapest Treaty? Please state which countries  
No other countries

After a U.S. Patent issues, the ATCC makes the culture available to anyone who requests it.

13. Do you wish the ATCC to inform you of all requests for this strain (Fee: \$330 for 30 years)? (This is allowed under the Treaty, but if you waive the right, the fee is reduced) No

14. Would you like to be notified via fax or telephone of the ATCC number assigned to your strain (Fee: \$10)? Yes  
Fax No. (405) 271-4110 Telephone No. (405) 271-7385

Attention (name of individual) Dr. Eugen Koren

15. Deposit and viability certificates should be directed to:

Dr. Eugen Koren

Oklahoma Medical Research Foundation

825 NE 13<sup>th</sup> Street, Oklahoma City, OK 73104

16. Payment by check, or credit card (MasterCard or VISA), must accompany the deposit unless prior arrangements for billing have been made and approved. If arrangements have been made to bill you for services an invoice should be sent to (include P.O. #):

Credit Card # (indicate MasterCard or VISA)

Expiration Date

Type or print the name shown on credit card

Signature

17. Name and address of attorney (to whom information will be made available if you complete):

18. Deposited on behalf of (must be completed): Dr. Eugen Koren, Oklahoma Medical Research Foundation

19. Additional comments:

I understand and agree that the deposit may not be withdrawn by me for the period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit), and that if a strain should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the case of viruses, cell cultures, plasmids and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

4/6/94

Eugen Koren

Date

Typed Name

Signature

Address: Oklahoma Medical Research Foundation

825 NE 13<sup>th</sup> Street, Oklahoma City, OK 73104

THIS FORM MUST BE COMPLETED IN ENGLISH

ADDRESS SHIPMENTS AND FIRM TO THE ATTENTION OF:

Mr. Bobbie A. Brandon  
American Type Culture Collection  
12301 Parklawn Drive  
Rockville, Maryland 20852 USA

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Form BP-1 (Page 2 of 2)